



Poppy Kendall
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Friday, June 18, 2004

Ref: Docket No. 2004N-0221

Dear Poppy:

ASKO Corporation is the manufacturer of the "Aloud" audio labeling system. The Aloud device was developed to assist those in the blind and visually impaired community maintain safe and accurate dispensing of their medications. In addition to the health and safety benefits the Aloud system enhances one's ability to independently manage their medication regimen.

ASKO Corporation has received the following awards and recognition for the benefits and technology of the Aloud audio labeling system:

- 1.) 1999 Certificate of Recognition. Awarded by the National Federation of the Blind to ASKO Corporation for generous assistance given to help the blind achieve better lives.
- 2.) 2001 Business of the Year. Awarded by the Delaware County Chamber of Commerce to ASKO Corporation for the introduction of the Aloud audio labeling system which has been lauded by the federal government and national associations for the blind.
- 3.) 2001 "Apple of Our eye". Awarded by the Dayle McIntosh Center to ASKO Corporation for valuable assistive technology for the blind and visually impaired.
- 4.) 2002 Access Award. Awarded by the American Foundation for the Blind to ASKO Corporation for providing a product that enhances the quality of life for those in the blind and visually impaired community.
- 5.) Basic ordering Agreement and JWOD status from the Department of Veterans Affairs. (BOA # NIB90505)

It is our experience that the biggest barrier in relation to the use of this type of assistive technology is the ability of the person in need to pay for the associated devices. We have discussed the use of this product with many people within the blind community, as well as state and federal blind agencies. Typical feedback stated that the device is very useful but may be cost prohibitive without some type of reimbursement program.

Included with this letter is a report of statistics, a pricing sheet, and a letter of support from the Central Association for the Blind and Visually Impaired. This information should answer the questions posted in docket #2004N-0221. I can be reached Monday through Friday to answer any additional questions. Samples will be provided upon request.

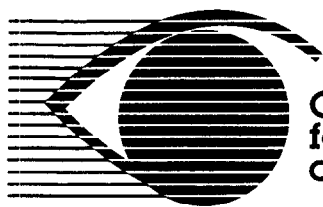
Thank you for your consideration.

Sincerely,

Vincent Pricolo
Sales Manager

2004N-0221

C10



**Central Association
for the Blind
and Visually Impaired**

507 Kent Street, Utica, NY 13501 • (315) 797-2233 • Toll Free: 877-719-9996 • FAX: Admin. 797-2244 • FAX: Mfg. 797-2250

Incorporated 1929

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www.cabvi.org

June 9, 2004

Mr. David Hartwell, President
Asko Corporation
2 South Street
Stamford, NY 12167

Dear David,

I'm writing to you regarding to the Medicare Study, Docket #2004N-0221 *Study on making Prescription Pharmaceutical Information Accessible for Blind & Visually Impaired Individuals*.

A significant part of staying healthy is being sure to take medications in the right amount and at the right time. For people who are blind or visually impaired, reading labels on prescription containers can be a real challenge and one of many potential threats to their independence and safety. Most people in this population are left to their own ingenuity to devise their own recognition systems such as attaching home-made Braille labels, storing medications in specific locations, or placing medications in different shaped bottles-methods that may be limited in terms of effectiveness and reliability. The Aloud system manufactured by your company is an inexpensive solution that can improve patient compliance when taking medication and help prevent dangerous dosage mistakes.

We were pleased that the American Foundation for the Blind recognized ASKO Corporation for creating the Aloud Audio Labeling System, by awarding them their 2002 Access Award in Washington, D.C. AFB's Access Award honors individuals, corporations, and organizations that are eliminating or substantially reducing inequities faced by people who are blind or visually impaired.

For the past two years, staff at our agency has had the opportunity to witness the value of the Aloud system for our visually impaired consumers. We fully endorse this product as an important step towards enhancing safety and independence for people who are visually impaired.

Sincerely,

Donald D. LoGuidice
President & CEO



Introducing the new Model 200 Aloud audio label system

Pricing:

Aloud model 200 - \$88.50

Includes recorder / player, microphone,
3 audio labels, 12 adhesive pads, battery
charger, earbud, instruction sheet

Extra audio labels - \$11.95 each

Reusable, attach to a new bottle and re-record
when prescription changes, 60 second length
for identifying additional medications

Polyethylene Adhesive pads

For attaching audio labels to bottles

round foam adhesive - \$4.75 per 100 pack

rectangular foam adhesive - \$5.25 per 50 pack



**Allowing the blind and
visually impaired to
hear the information
that is printed on their
prescription labels.**

**To order Aloud, or for more
information please contact us**



ASKO Corporation

2 South Street / Stamford, NY 12167

877-732-9227 607-652-3315 fax 607-652-3653

www.askocorp.com sales@askocorp.com



Digital Audio Labeling System

Allowing people who are blind and visually impaired to hear the information that is printed on their prescription labels



PRICING

Aloud Model 200 ~ \$69.99

NSN 6515-00-NIB-0226

Includes recorder/player, microphone, 3 audio labels, 12 adhesive pads, battery charger, earbud, instruction sheet

CONVENIENT

PORTABLE

RECHARGEABLE

HIGH FIDELITY AUDIO

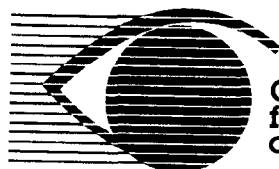
Extra Audio Labels ~ \$10.99 each

NSN 6515-00-NIB-0227

Reusable, attach to a new bottle and re-record when prescription changes, 60 second length for identifying additional medications

Polyethylene Adhesive Pads

For attaching audio labels to bottles
round foam adhesive \$4.75 per 100 pack
rectangular foam adhesive \$5.25 per 50 pack



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and Visually Impaired**

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www.cabvi.org

Javits-Wagner-O'Day
JWOD

DEFINITIONS

Non-correctable Vision Impairment:

This includes blindness in one or both eyes, or the inability to recognize a friend across the room, or the inability to read regular newspaper print, or self-reported poor or very poor vision, or report of any other trouble seeing even when wearing glasses or contact lenses

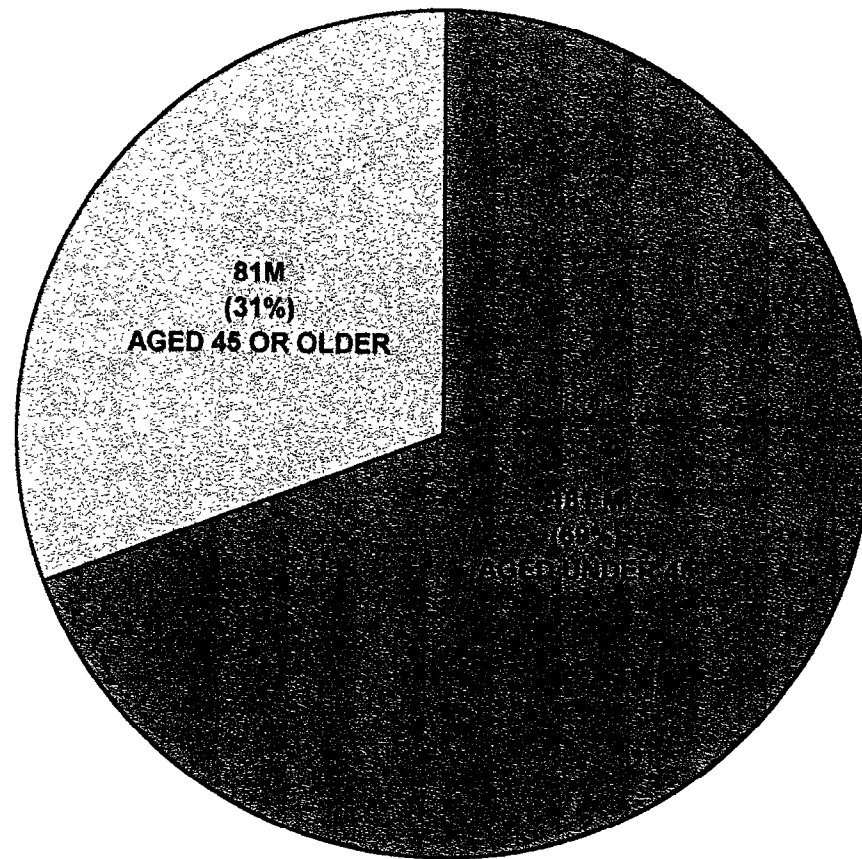
Severe Vision Impairment:

Defined as an inability to recognize a friend at arm's length, or cannot read ordinary newspaper print, or reports poor or very poor vision, or is blind in both eyes even when wearing glasses or contact lenses

Legally Blind:

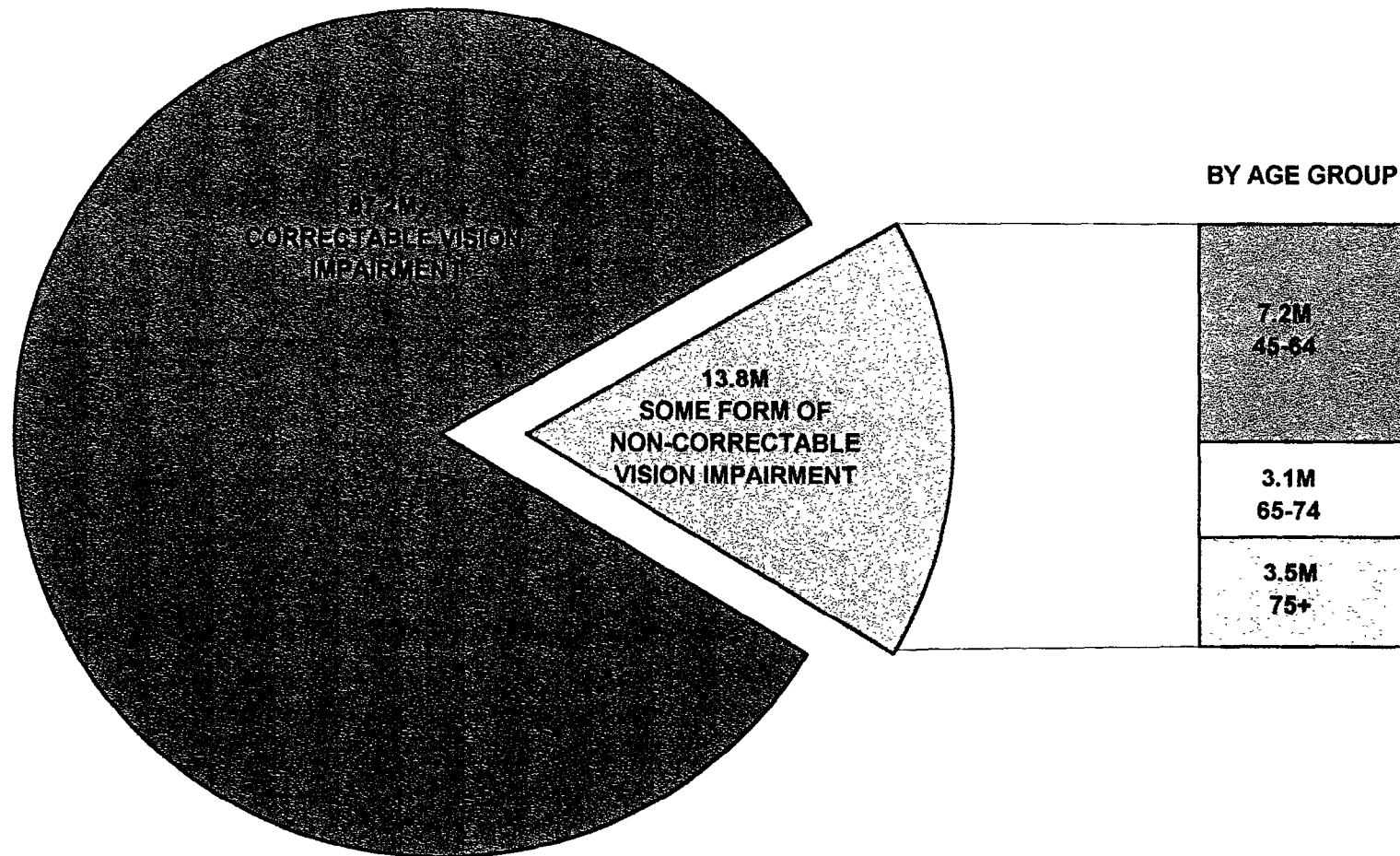
Defined as clinically measured visual acuity of 20/200 or less or a visual field in the better eye after optimal correction of 20 degrees or less

TOTAL US POPULATION (262M)



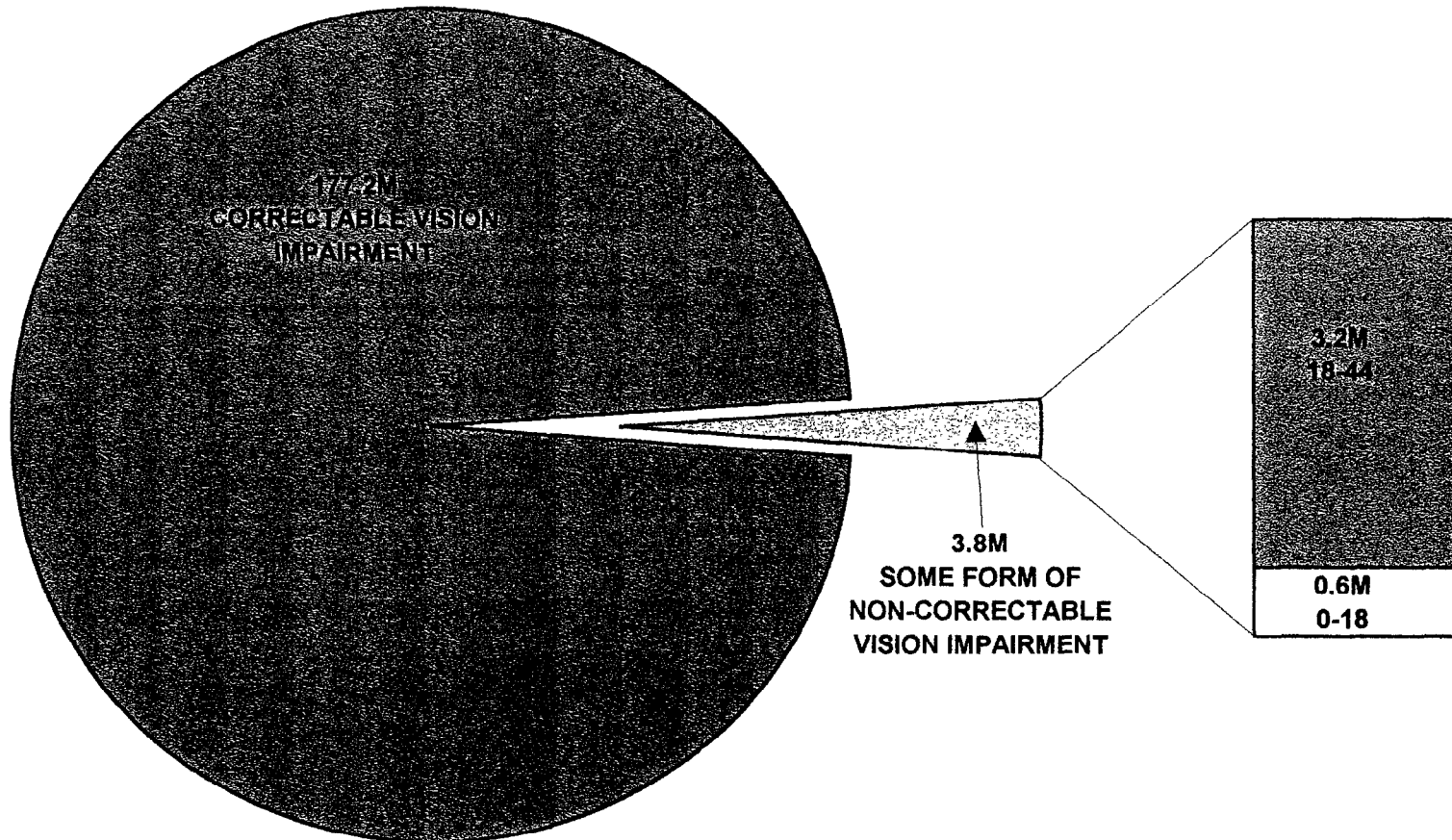
Source: *The Lighthouse National survey: 1995*

US POPULATION - 45 OR OLDER (81M)

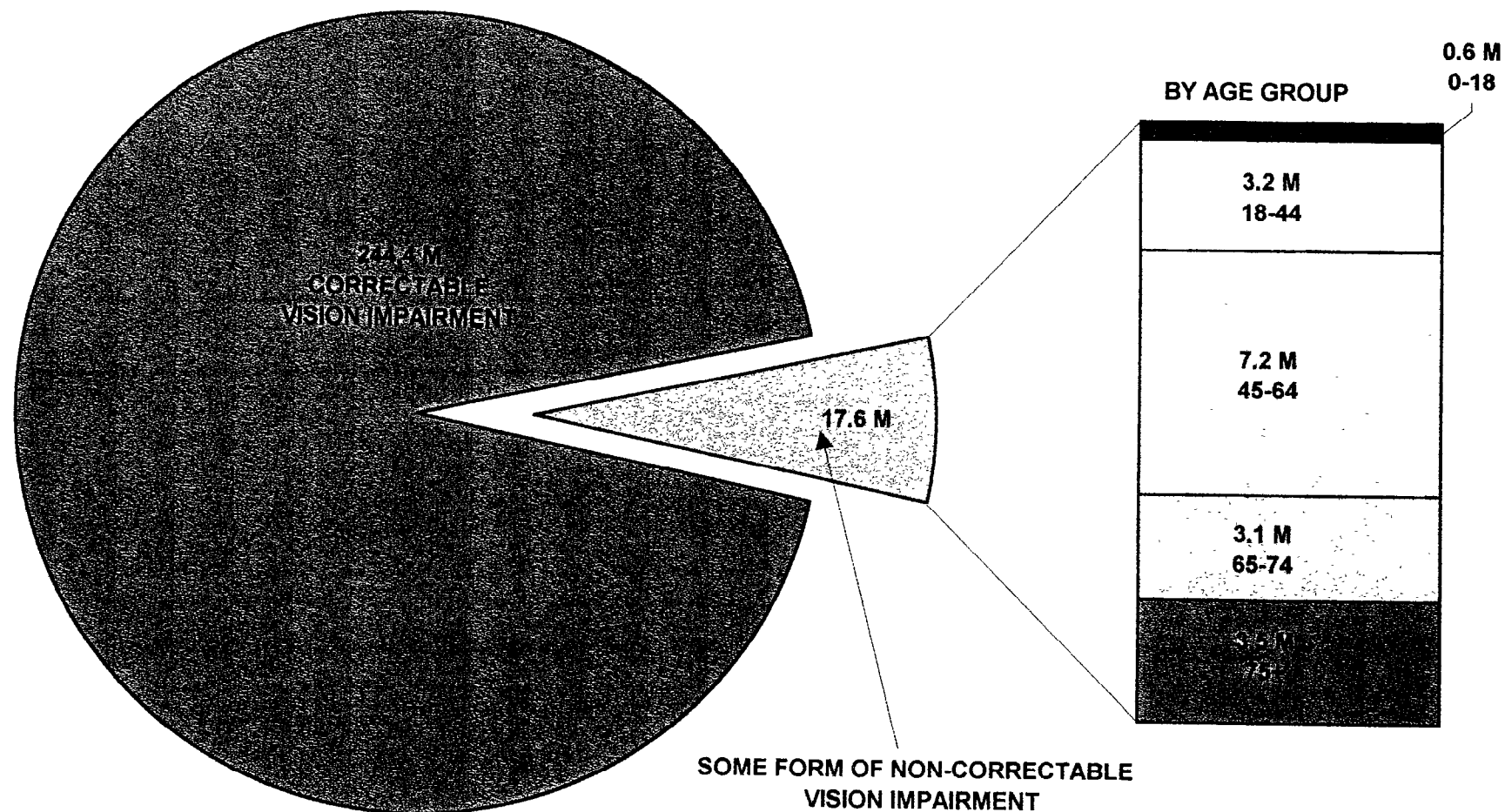


Source: The Lighthouse National Survey:1995

US POPULATION - UNDER 45 (181M)

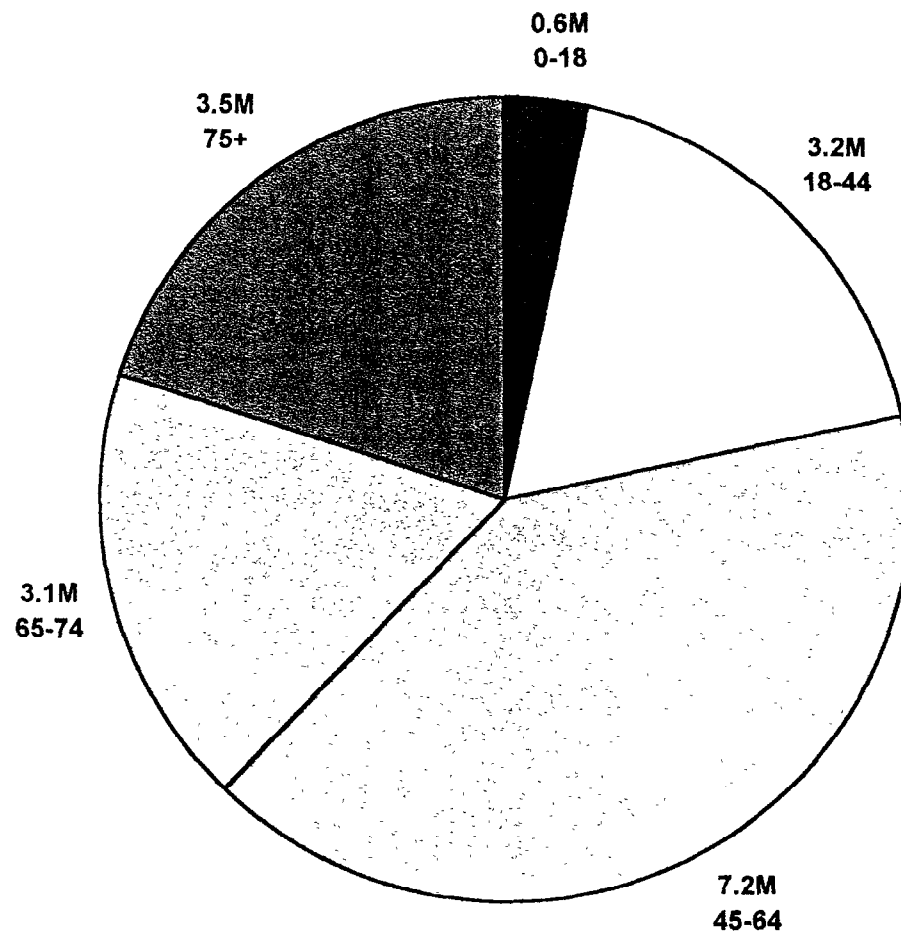


TOTAL US POPULATION OF (NON-CORRECTABLE) VISUALLY IMPAIRED



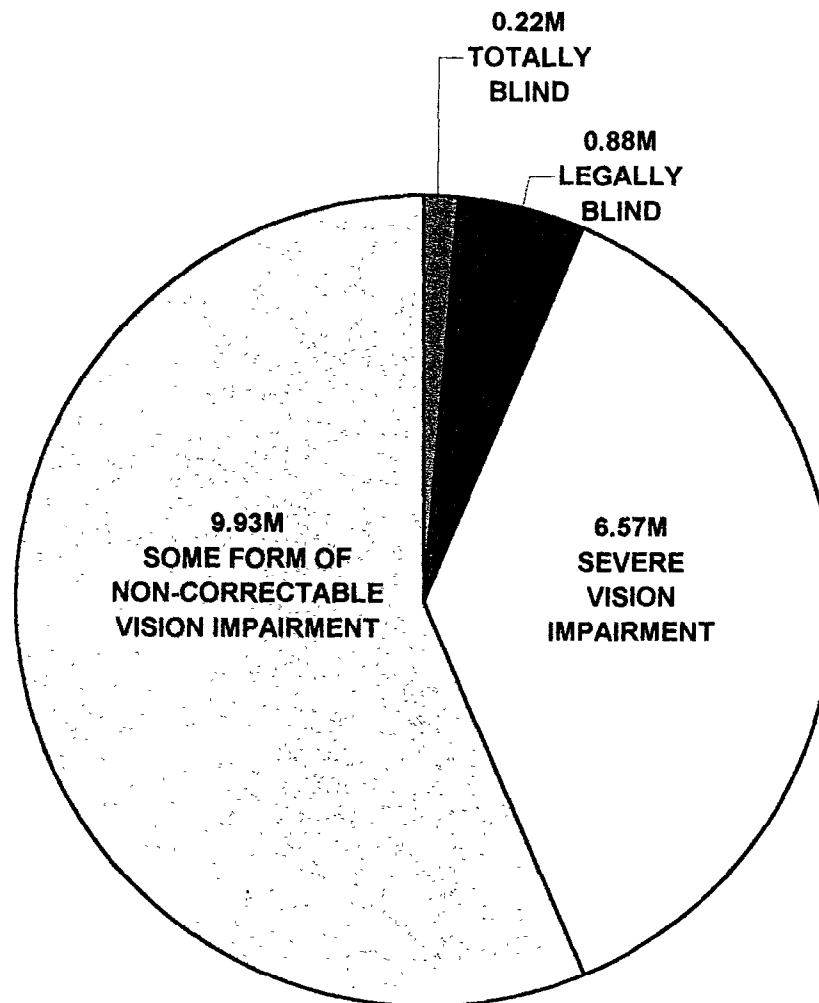
Source: Adams & Marano, 1995, Estimates from National Health Interview Survey, 1994
The Lighthouse National Survey: 1995

US POPULATION OF (NON-CORRECTABLE) VISUALLY IMPAIRED (17.6M)
BY AGE GROUP



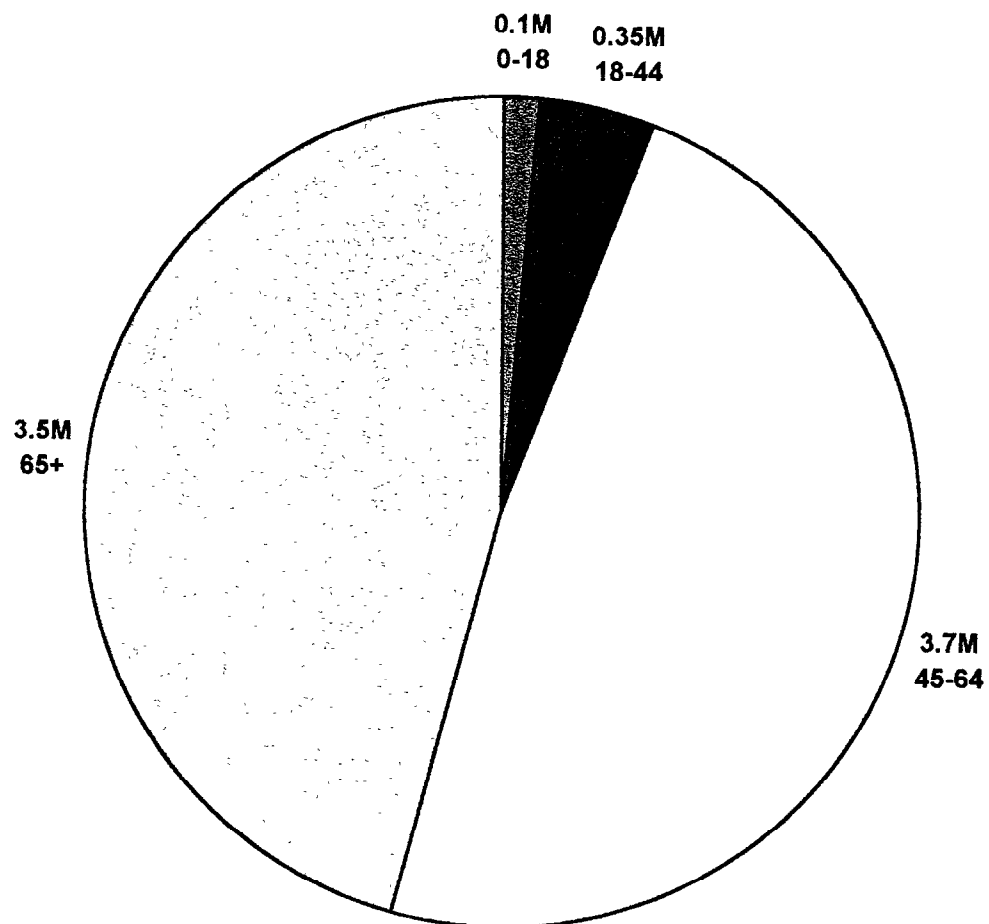
Source: Adams & Marano, 1995; Estimates from National Health Interview Survey, 1994
The Lighthouse National survey: 1995

US POPULATION OF (NON-CORRECTABLE) VISUALLY IMPAIRED (17.6M)
BY CATEGORY



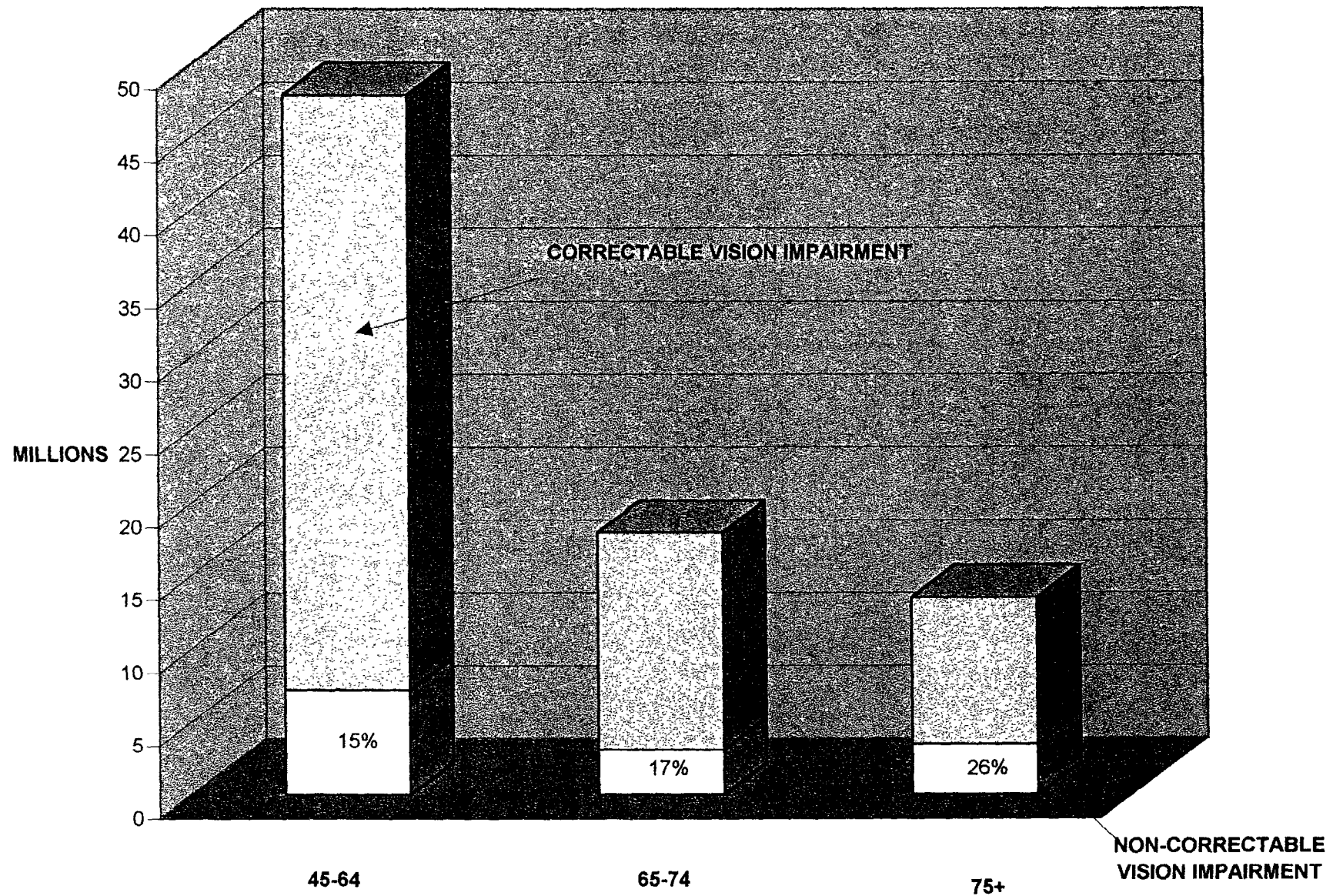
Source: *The Lighthouse National Survey: 1995*
American Foundation for the Blind, 1989
Chiang, Bassi, & Javitt, 1992
Adams & Marano, 1995, Estimates from National Health Interview Survey, 1994

US POPULATION OF SEVERELY VISUALLY IMPAIRED (7.65M)
BY AGE GROUP

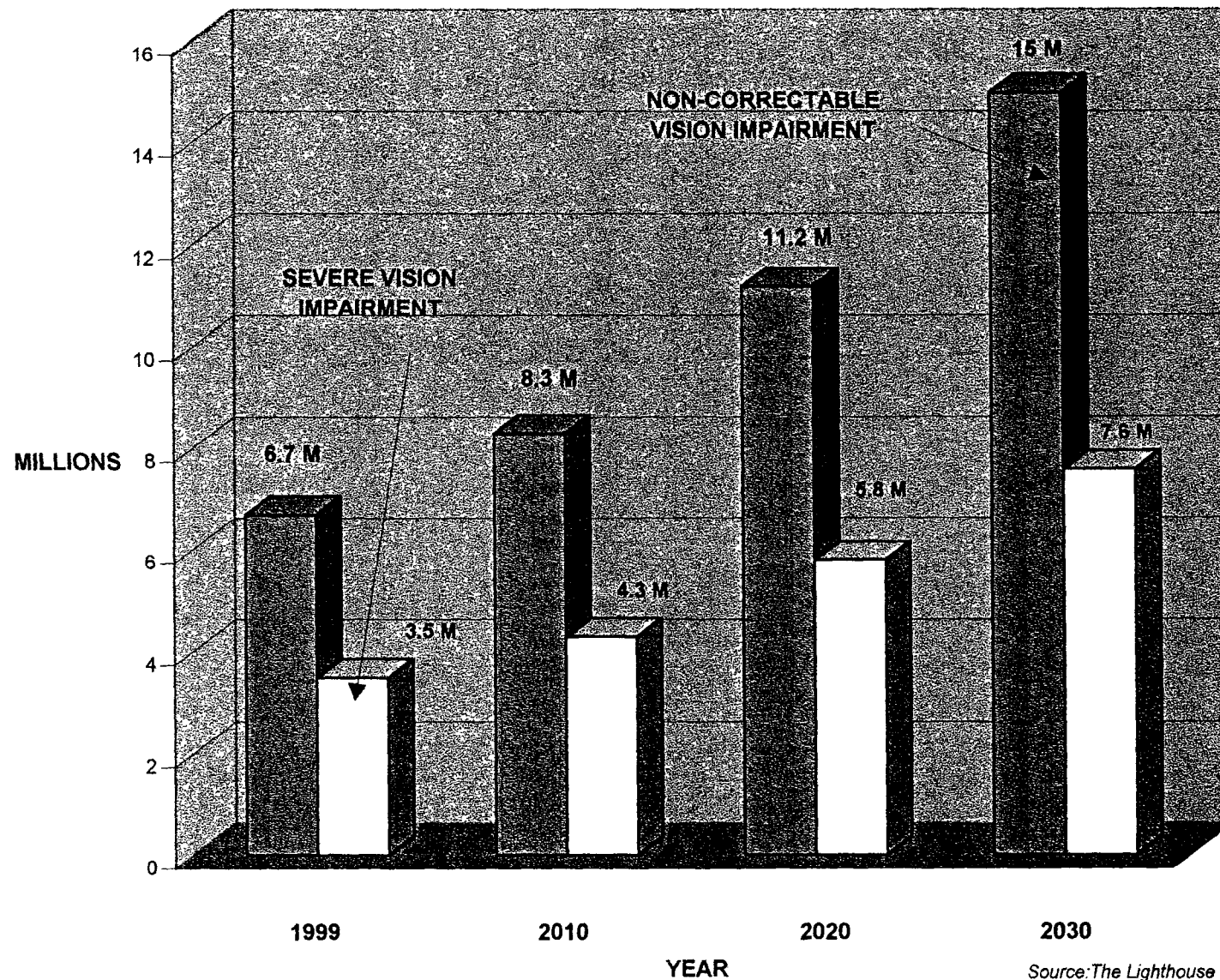


Source: Nelson & Dimitrova, 1993; based on 1990 estimates
The Lighthouse National Survey: 1995

PERCENTAGE OF (NON-CORRECTABLE) VISUALLY IMPAIRED
BY AGE GROUP



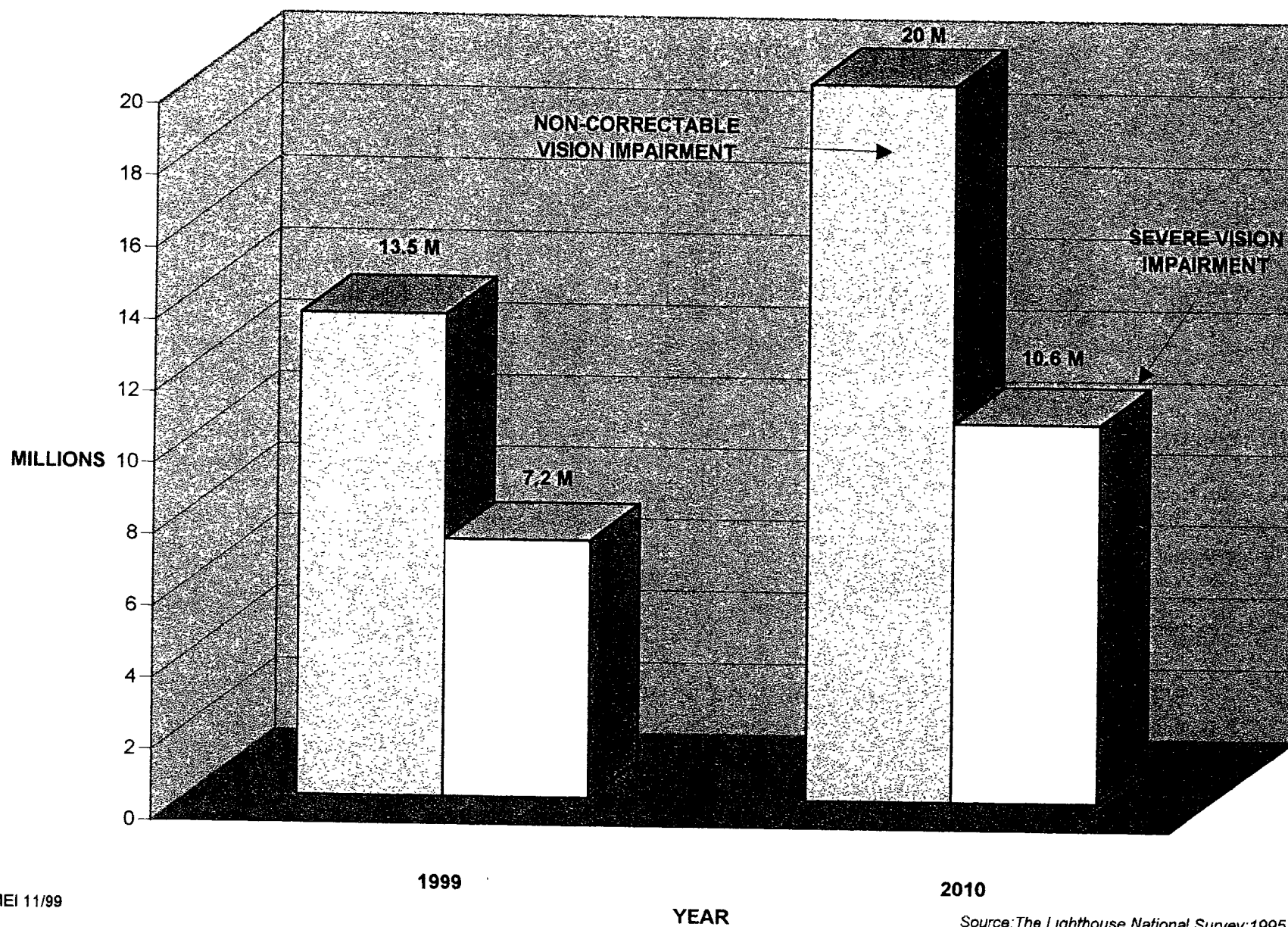
GROWTH OF US VISUALLY IMPAIRED POPULATION: 65+



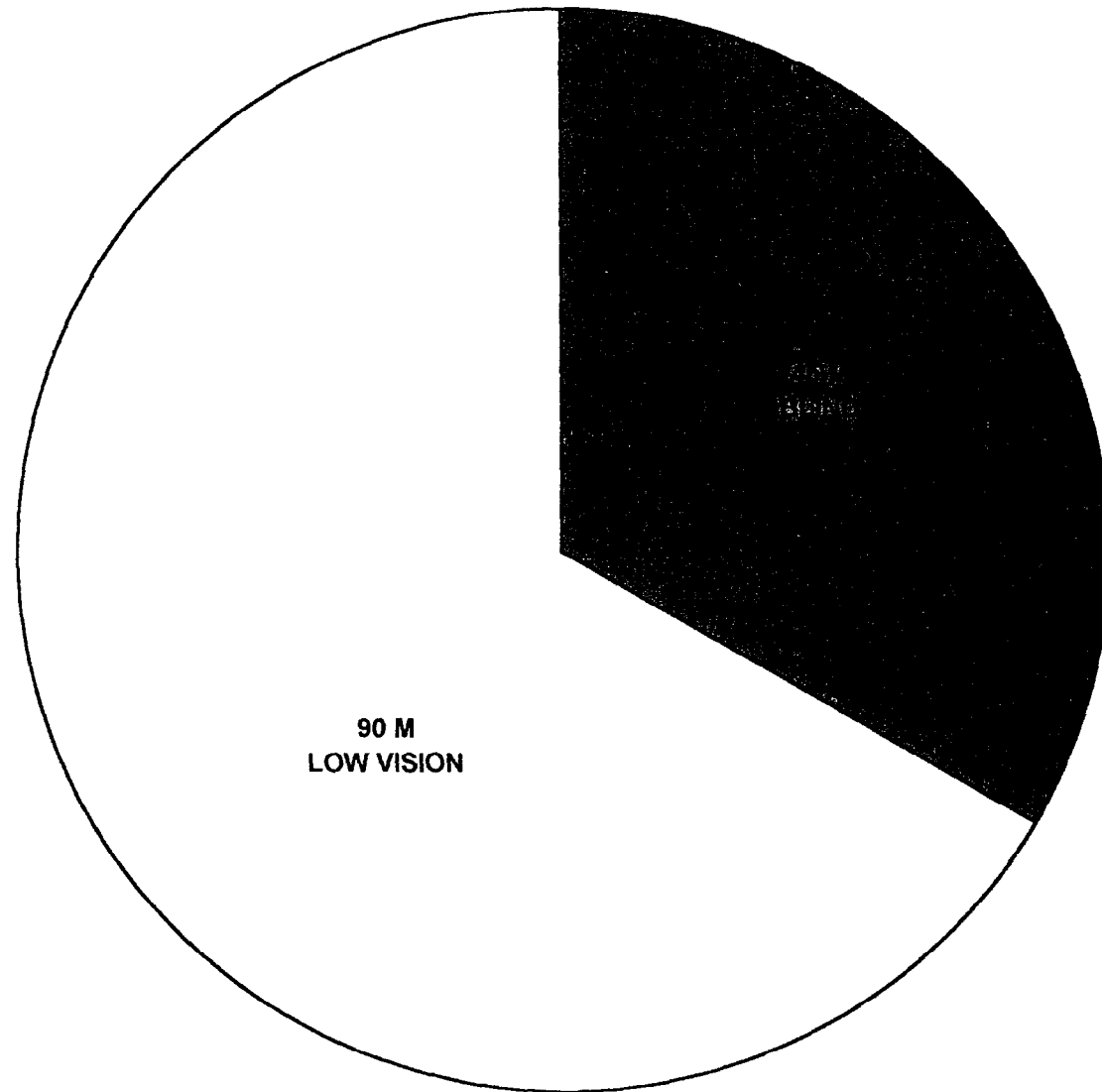
US Visually Impaired Population: 65+**By State**

STATE	POPULATION 65+	# WITH VISION IMPAIRMENT	
Alabama	568,352	119,354	
Alaska	33,556	7,047	
Arizona	617,538	129,68	
Arkansas	363,232	76,279	
California	3,614,632	759,073	
Colorado	401,784	84,375	
Connecticut	469,112	98,513	
Delaware	96,326	20,228	
District of Columbia	72,710	15,269	
Florida	2,734,145	574,170	
Georgia	755,092	158,569	
Hawaii	158,306	33,244	
Idaho	139,126	29,216	
Illinois	1,495,969	314,153	
Indiana	739,587	155,313	
Kansas	354,113	74,364	
Kentucky	492,856	103,500	
Louisiana	503,750	105,788	
Maine	174,832	36,715	
Maryland	591,545	124,224	
Massachusetts	860,604	180,727	
Michigan	1,223,040	256,838	
Minnesota	583,097	122,450	
Mississippi	336,311	70,625	
Missouri	745,387	156,531	
Montana	117,038	24,578	
Nebraska	228,735	48,034	
Nevada	200,335	42,070	
New York	2,423,797	508,997	
New Mexico	198,038	41,588	
New Jersey	1,105,816	232,221	
New Hampshire	142,298	29,883	
North Dakota	91,976	19,315	
North Carolina	946,753	198,818	
Ohio	1,500,851	315,179	
Oklahoma	448,388	94,161	
Oregon	432,718	90,871	
Pennsylvania	1,904,312	399,906	
Rhode Island	154,327	32,409	
South Dakota	105,742	22,206	
Tennessee	679,212	142,635	
Texas	1,999,751	419,948	
Utah	184,098	38,661	
Vermont	72,573	15,240	
Virginia	766,976	161,065	
W. Virginia	274,689	57,685	
Washington	651,970	136,914	
Wisconsin	690,786	145,065	
Wyoming	55,527	11,661	
TOTAL	33,501,708	6,779,274	20.24%

GROWTH OF US VISUALLY IMPAIRED POPULATION: 45+



NON-CORRECTABLE VISION IMPAIRMENT - WORLDWIDE (135M)



800-533-7863
607-652-7305

FAX 607-652-3653



AUDIOSEARS CORPORATION

2 South Street, Stamford, New York 12167

vpricolo@audiosears.com
www.audiosears.com

Vincent Pricolo
Sales Manager



ASKO Corporation

2 South Street Stamford, New York 12167

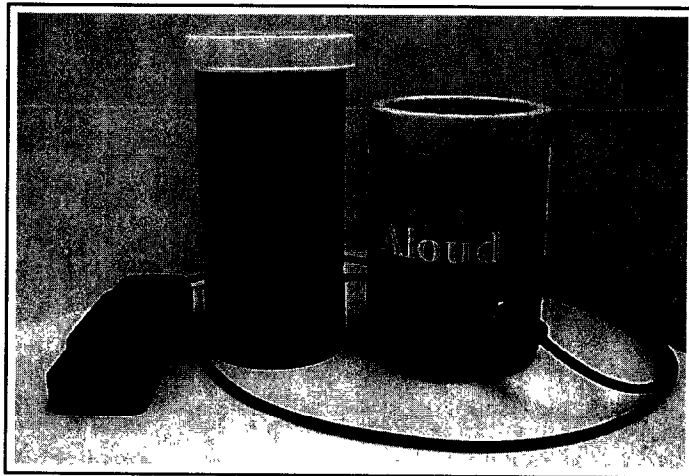
e-mail: vpricolo@audiosears.com
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Aloud[®]

**Audio Labeling System
Model 200**



**Product Description
&
Operating Instructions**

Introduction

The Aloud Audio Labeling System provides a safe and reliable means for qualified individuals to record and attach to medication containers an audio version of the printed prescription label. The "audio label" can be later replayed as often as needed by the patient. The Aloud System has been developed to assist the blind and visually impaired to identify medications and comply with the prescribed regimen. It is also ideal for the elderly, illiterate and in situations where language differences can cause confusion.

System Description

The Aloud Audio Labeling System consists of three components:

- *Audio Label - attached to the medication container and contains the recorded prescription information.
- *Recording Microphone - used by a qualified individual to record onto the Audio Label a spoken message of up to sixty seconds in duration.
- *Model 200 Player/ Recorder - used to both record and replay the "audio label" message.

The "audio label" is a small, re-usable, enclosure containing the memory which retains the spoken message. When the patient requires a prescription refill, the "audio label" can be removed from the original medication container by slowly peeling apart the empty container from your "audio label". A new message is recorded after you've attached your "audio label" to the new prescription medication container using a fresh Aloud foam adhesive. The above procedure is repeated each time the patient requires a new prescription or refill.

The "recording microphone" is used by any qualified individual to record a spoken version of the printed prescription label onto the "audio label" in conjunction with the recording capability of the Aloud Model 200 player/ recorder.

The "Model 200 Player / Recorder" contains all the support electronics to allow for both the recording and replay of the "audio label" after it is attached to the medication container. The message can be replayed an indefinite number of times and cannot be accidentally erased or altered by the patient.

Attention

While the manufacturers want to see as much benefit as possible from the Aloud Audio Labeling System, the Aloud "audio label" is provided without any pre-recorded messages. ASKO is not responsible, and shall bear no liability, for the content of any information recorded on this product by the purchaser or any other person. Since it is foreseeable that a visually impaired person could rely upon information heard from this product, the person dictating the information to the Aloud "audio label" should exercise due care and caution.

Prescription Bottle
with Audio Label



Aloud Audio Labeling System

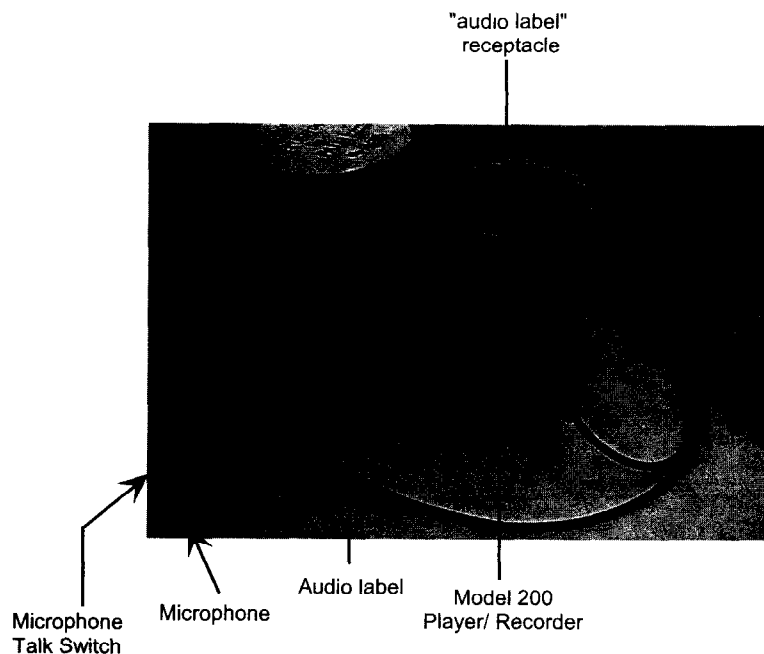


FIGURE 2

Aloud Model 200 Player / Recorder Unit Setup and Operation

The Aloud Model 200 Player / Recorder consists of the following items:

- *Replay unit
- *Microphone assembly
- *Foam dhesives
- *AC adapter
- *Protective cover
- *Operating Instructions

To prepare the Aloud Model 200 for use, connect the AC adapter cable into the "AC adapter" socket and plug the AC adapter into a 110V wall outlet. This should be left connected overnight to charge the battery the first time.

Prior to recording an "audio label" for a prescription the printed prescription label must be produced using normal pharmacy practice and procedure and attached to the medication container. The content of the "audio label" should duplicate the information provided on the printed prescription label only and is solely the responsibility of the person recording the message onto the "audio label".

To Record an Audio Label

The following recording procedure is used for both new and previously recorded "audio labels". The recording process automatically erases any previously recorded messages. The internal battery must be charged to perform a recording operation.

1. Attach an "audio label" to whatever container you choose using an Aloud adhesive disc or pad whichever is appropriate.
2. Remove the protective covers from the Aloud Model 200 and "audio label", if they are installed.
3. Insert the microphone connector into the jack labeled "AC - MIC" on the Aloud Model 200 player / recorder.
4. Insert the "audio label" into the "audio label receptacle" on the Aloud Model 200 player / recorder and apply and maintain a slight downward pressure.
5. If there is a previous message recorded on this "audio label" you will hear it begin to play back. At any time you may push and hold the "Talk" button and you can begin recording your message (up to the capacity of the audio label, i.e. 30-60 seconds) speaking into the open end of the microphone.
6. When you have completed recording your message, release the "Talk" button and you will immediately hear played back the message that you just recorded. If it is to your satisfaction, you can remove the "audio label" from your Aloud Model 200 player / recorder. If you'd like to change your message, simply go back to step 5 and record a new message.

To Replay an Audio label

1. Remove the protective covers from the Aloud Model 200 and "audio label" if they are in place.
2. To replay a message using the Aloud Model 200 simply insert the "audio label" into the audio label receptacle on the Aloud Model 200 and apply and maintain a slight downward pressure. The message will begin to play. The "audio label" message will play as long as you maintain pressure or until the end of the message is reached. If you remove and then re-apply pressure to the "audio label" before the end of the message, the Aloud Model 200 will automatically re-start the message from the beginning.
3. If you desire private listening, an earphone is provided and can be inserted into the front jack labeled "EARPHONE". Inserting the earphone will disconnect the internal speaker.
4. Playing messages can be accomplished using either the built in rechargeable battery, or the supplied AC adapter.

If the message needs to be changed or re-recorded follow the "To Record an Audio Label" procedure above.

Precautions

Your Aloud System has been designed and manufactured using high quality components and should provide years of service. There are no hazardous voltages present in either the Aloud Model 200 or the Aloud "audio label" and the following precautions will help to ensure product reliability.

- * Always use the protective covers when the system is not in use and when shipping "audio labels".
- * Keep the Aloud System away from sources of extreme heat, such as stoves, radiators, heat registers and other similar appliances.
- * Do not immerse either the Aloud Model 200 or "audio labels" in water or allow moisture or fluids to penetrate inside.
- * Any fluid spills should be shaken off immediately and allowed to dry at room temperature before attempting to use.

There are no user serviceable parts inside your Aloud Audio Labeling System and no attempt should be made to open or repair any of the components.

Battery Operation

Your Aloud Model 200 will likely arrive to you with it's rechargeable battery in a discharged condition. For all recording operations, and cordless replay operations, the battery must be charged. This is accomplished by connecting the supplied AC adapter to the jack on your replay unit marked "AC / MIC" and plugging it into a standard 110V home outlet for 6 hours or more. Your Aloud Model 200 should operate for several weeks before requiring recharging.

To help you identify a low battery condition, there is a built in low battery warning. When your battery requires charging your replay unit will beep shortly at the beginning of each replay cycle.

Customer Service

Your satisfaction with the ASKO Aloud Audio Labeling System is our number one priority. If you need help with the operation of your Aloud system, require technical service or would like to place an order please contact ASKO at 877-732-9227 and ask for an Aloud customer service representative.

Aloud Warranty

Your ASKO Aloud Model 200 is warranted against defects in material or workmanship to you, the original owner, for one year from the original date of purchase, subject to the limitations below. If this Aloud Model 200 fails due to defects in manufacturing, as diagnosed by an authorized ASKO service representative, we will repair the product without charge, or replace it, at our option.

This limited one year warranty applies to defects in materials and workmanship. Product failure resulting from accidents, improper care, or operation, or negligence, where ASKO is not at fault, or from normal wear and tear, is not considered a "defect," in these cases, repairs or replacements will be made at a reasonable charge.

This warranty shall not apply to consumable parts such as cords, or earphones. This warranty does not apply to any unit which has been subject to alteration or modification, or used in any manner contrary to written instructions given by ASKO. This warranty is void if service is performed by a resource other than ASKO Service. No responsibility is assumed for any incidental or consequential damages.